



US009918635B2

(12) **United States Patent**
Bousamra et al.

(10) **Patent No.:** US 9,918,635 B2
(45) **Date of Patent:** Mar. 20, 2018

(54) **SYSTEMS AND METHODS FOR OPTIMIZING INSULIN DOSAGE**

(75) Inventors: **Steven Bousamra**, Carmel, IN (US); **Stefan Weinert**, Pendleton, IN (US); **Juergen Rasch-Menges**, Schwetzingen (DE); **P. Douglas Walling**, Indianapolis, IN (US); **John F. Price**, Mc Cordsville, IN (US); **Heino Elkmeier**, Lorsch (DE); **Birgit Kraeling**, Fussgoenheim (DE); **Karl Werner**, Wiesloch (DE); **Ulrich Porsch**, Weinheim (DE)

(73) Assignee: **Roche Diabetes Care, Inc.**, Indianapolis, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 58 days.

(21) Appl. No.: 12/818,310

(22) Filed: Jun. 18, 2010

(65) **Prior Publication Data**

US 2011/0015511 A1 Jan. 20, 2011

Related U.S. Application Data

(63) Continuation-in-part of application No. 12/643,338, filed on Dec. 21, 2009.
(Continued)

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/145 (2006.01)

(Continued)

(52) **U.S. Cl.**
CPC *A61B 5/0002* (2013.01); *A61B 5/14532* (2013.01); *A61B 5/14546* (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC ... A61B 5/05; A61B 5/14532; A61B 5/14546;
A61M 31/00; A61M 2230/201; C12Q
1/006

(Continued)

(56)

References Cited

U.S. PATENT DOCUMENTS

4,151,845 A	5/1979 Clemens
4,731,726 A	3/1988 Allen, III

(Continued)

FOREIGN PATENT DOCUMENTS

CN 1326162 A	12/2001
CN 1755700 A	4/2006

(Continued)

OTHER PUBLICATIONS

Non-final Office Action pertaining to U.S. Appl. No. 12/643,338 dated Apr. 26, 2012.

(Continued)

Primary Examiner — Puya Agahi

(74) *Attorney, Agent, or Firm* — Dinsmore & Shohl LLP

(57) **ABSTRACT**

Embodiments of a testing method suitable for diabetic persons to optimize their administered insulin dosage comprise collecting one or more sampling sets of biomarker data, wherein each sampling set comprises a sufficient plurality of non-adverse sampling instances and wherein each sampling instance comprises an acceptable biomarker reading at a single point in time recorded upon compliance with adherence criteria, determining a biomarker sampling parameter from each sampling set, comparing the biomarker sampling parameter to a target biomarker range, calculating an insulin adjustment parameter associated with the biomarker sampling parameter if the biomarker sampling parameter falls outside the target biomarker range, adjusting the insulin dosage by the insulin adjustment parameter if the biomarker sampling parameter falls outside the target biomarker range and if the insulin dosage does not exceed maximum dosage, and exiting the testing method if the adjusted insulin dosage is optimized. The insulin dosage is optimized when one or more biomarker sampling parameters fall within a target biomarker range.

32 Claims, 9 Drawing Sheets

